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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/814,125	04/01/2004	Johan Frostegard	FROSTEGARD=1D	8029

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EXAMINER	
COOK, LISA V	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/814,125	FROSTEGARD, JOHAN	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/720,967.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *attached*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Currently claims 1-20 are pending and under consideration.

Priority

2. The first line of the specification should be updated to include US Patent #6,780,605. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also, the current status of all nonprovisional parent applications referenced should be included. Please include US Patent #6,780,605.

Drawings

3. No drawings were filed in this application.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 or applicant on form PTO-1449 cited the references they have not been considered.

5. The Information Disclosure Statement filed 01 April 2004 has been consider as to the merits prior to first action.

6. The Information Disclosure Statement filed 12 August 2005 has been consider as to the merits prior to first action.

7. The Information Disclosure Statement filed 02 December 2005 has been consider as to the merits prior to first action.

Specification

8. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

I. Page 1 of the specification is not numbered. Appropriate correction required.

II. On page 5 line 24 section 0013 a typo appears "normotensive men the." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 2 and its dependent claims 3-7 and 17-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. The term "early" in claim 2 is a relative term, which renders the claim indefinite. The term "early" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Will the measurement indicate atherosclerosis or not? Please remove the term from the claim.

B. Claim 2 is vague and indefinite because it is not clear how a diagnosis of cardiovascular disease will also determine independent disorders like early atherosclerosis, hypertension, and thrombosis. If applicant intends to imply that the kit further detects or measures early atherosclerosis, hypertension, and thrombosis in addition to cardiovascular disease, then that should be clearly recited in the claim. Please clarify.

Please note: examiner was unable to ascertain if the instant claims were restricted from application number 09/720,967 now US Patent #6,780,605. Applicant is invited to shown evidence of such a restriction requirement.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-20 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-13 of US patent #6,780,605.

Both inventions are drawn to methods of evaluating cardiovascular disease from the measurement of the presence and/or concentration of antibodies to PAF or antibodies to phosphocholine. Thus the inventions read on the same scope measuring the same disorder (cardiovascular disease) and detecting the same antibodies (aPAF). Accordingly, the instant method is encompassed by US Patent #6,780,605.

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

I. Claims 1-13 are rejected under 35 U.S.C.103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view Ostermann et al. (Thrombosis Research, 52, 529-540, 1988).

Barquinero et al. teach an ELISA assay to measure antibodies against platelet-activating factor (PAF) in patients with autoimmune diseases. Specifically blood sample from patients with SLE (systemic lupus crythematosus), PAPS (antiphospholip syndrome), and syphilis. SLE is vascular diseases (relating to blood vessels). SLE includes severe inflammation of blood vessels (see The signet Mosby medical encyclopedia definition attached). See abstract and page 55 Introduction and page 56 "ELISA technique for anti-PAF".

With respect to the means for determining patients at risk for having cardiovascular disease and/or early atherosclerosis, it is noted that Barquinero et al. teach the measurement of PAF in patients with autoimmune disease such as SLE. SLE includes blood vessel inflammation, which could lead to cardiovascular disease (risk). Since there is no corresponding structure, etc., in the specification to limit the means step or step plus function limitation, an equivalent is any element that performs the specified function.

Barquinero et al. differs from the instant invention in not specifically teaching PAF as an indicator for cardiovascular diseases such as atherosclerosis via PAF quantification in serum and plasma.

However, Ostermann et al. teach PAF quantification in serum and plasma as well as its correlation/diagnosis (discrimination) in Atherosclerotic patients. See abstract and page 531 2nd paragraph. Thirty-Six health volunteers and 40 atherosclerotic patients were evaluated in the study. Blood samples were analyzed to determine PAF concentration.

The results showed a significant increase in serum PAF levels of patients suffering from coronary artery disease. Page 536, last paragraph. The researchers also measured plasma levels. See page 538.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to measure PAF concentrations in serum and plasma patients with cardiovascular disease such as atherosclerosis as taught by Ostermann et al. in the method of Barquinero et al. because Osterman et al. teach the critical role of PAF in myocardial infarction/atherosclerosis and its accuracy of correctly classifying subjects. See abstract. Ostermann et al. further teach that PAF could discriminate between low and high-risk groups and was an improvement over other commonly utilized discriminators (total cholesterol, VLDL/LDL-cholesterol, apo). See page 537 2nd paragraph.

One having ordinary skill in the art would have been motivated to do this because the early detection of such disorders is both beneficial in possible prevention and treatment of the disease.

II. Claims 14-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Ostermann et al. (Thrombosis Research, 52, 529-540, 1988) and further in view of Karasawa et al.(Lipids, Vol. 26, No. 12, 1991, pages 1122-1125).

Please see Barquinero et al. in view of Ostermann et al. as set forth above.

Barquinero et al. in view of Ostermann et al. differ from the instant invention in not specifically teaching the detection of various known naturally occurring phospholipids related to PAF(phospholine). These forms include lyosPAF , PC(phosphatidylcholine), and lysoPC(lysophosphatidylcholine).

However, Karasawa et al. disclose systems to detect antibodies to PAF. The reference further evaluates related phospholipids (PC, lysoPC, lysoPAF, PE, PS, PG, PI, PA, SM, and CL). See abstract. Each phospholipids reacts differently with regard to binding antibodies to PAF. In some instances the related phospholipids cross react with PAF antibodies. See page 1123 Results. This cross-reaction could result in erroneous results in PAF antibody levels.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use various known PAF related phospholipids to evaluate cross reactivity and allow for accurate detection of PAF antibodies as taught by Karasawa et al. in the kit of Barquinero et al. (Lupus, 1994, 3, 55-58) in view of Ostermann et al. because Karasawa et al. disclosed that these related PAF phospholipids could possible cross-react with PAF. See page 1125.

One having ordinary skill in the art would have been motivated to do this to account for cross-reactivity and provide accurate detection of aPAF (antibodies to PAF).

13. For reasons aforementioned, no claims are allowed.

Remarks

14. Prior art made of record and not relied upon is considered pertinent to the applicant's disclosure:

A. Baldo et al. (LIPIDS, Vol26, No.12, 1991, 1136-1139) teach an immunoassay technique to measure PAF

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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